

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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Ex parte MITSUSHI HIKIDA and MASAOKI HAYASHI

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Appeal No. 2002-1575  
Application No. 08/945,901

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ON BRIEF

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Before ADAMS, GREEN, MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the  
examiner's final rejection of claims 4, 5, 8-15, 21, and 24-30, which are all the  
claims pending in the application.

Claim 4 is illustrative of the subject matter on appeal and is reproduced  
below:

4. A method for reducing postoperative astigmatism by increasing the  
strength of a wound closure site comprising administering to the eyes  
of a patient after sclerocorneal incision or corneal incision, a  
pharmaceutically effective amount of lactoferrin in a concentration of  
0.1 to 1.05 (w/v).

The reference relied upon by the examiner is:

Mita et al. (Mita)

5,561,109

Oct. 1, 1996

### GROUND OF REJECTION

Claims 4, 5, 8-15, 21, and 24-30 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Mita.

We reverse.

### DISCUSSION

Mita teach a method for healing wounds caused by corneal injury, which includes administering to a patient an effective wound healing amount of lactoferrin either alone or in admixture with a least one excipient. Abstract. Mita disclose (column 1, lines 57-60) that their method is useful for treatment of various corneal disorders such as corneal injury caused by ulceration, inflammation or ophthalmological surgery. In addition, Mita disclose that the concentration of lactoferrin in an eye drop formulation would preferably be 0.01-3.0%. Column 2, lines 2-5. However in describing the best mode for carrying out their invention, Mita disclose the use of a 0.5% (w/v) lactoferrin formulation. Column 2, lines 11-25.

The examiner finds (Answer, page 4), “[t]he method steps in Mita are identical to the method steps of the instant invention in that they comprise administering to the eyes of a patient a pharmaceutically effective amount of lactoferrin.” In addition, the examiner finds (Answer, page 5), “as lactoferrin in the method of Mita is used in the same way and at the same amount as in the instant case, the specific effect of increasing the strength of the wound closure in [sic] inherently present in the referenced method.” According to the examiner

(id.), “[u]nder the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art.”

THE REJECTION UNDER 35 U.S.C. § 102:

A preamble to a claim “has the import that the claim as a whole suggests for it.” Bell Communications Research, Inc. v. Vitalink Communications Corp., 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). We note that a preamble is limiting when it is necessary to give life, meaning and vitality to the claims. Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481(CCPA 1951) (stating that a preamble is limiting when it is “necessary to give life, meaning and vitality to the claims or counts”). On this record the examiner recognizes (id.), Mita “does not specifically recite prevention of postoperative astigmatism or increasing the wound closure strength after corneal incision as claimed in the instant invention....” In our opinion, the examiner has considered the preamble as giving meaning and purpose to the manipulative step. Accordingly, we interpret the phrase “reducing postoperative astigmatism by increasing the strength of a wound closure site” as a positive limitation in appellants’ claimed method. Our decision is based on this interpretation.

To make up for the deficiency in Mita, the examiner finds (id.), Mita inherently meets the requirements of the preamble. According to the examiner (id.) “[u]nder the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art.” See e.g., In re

King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (CAFC 1986). It is, however, well established that an anticipating reference “must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.” PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). As set forth in Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749-50 (Fed. Cir. 1991) (citations omitted), inherency “may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.” Instead, the natural result flowing from the method disclosed in Mita must result in the performance of the questioned function.

In this regard, appellants point out (Brief, page 7), “[i]t has been reported<sup>[1]</sup> that a compound which exhibits a corneal wound healing effect by a stimulative effect on the proliferation of corneal keratocytes does not always exhibit a strength of a wound closure site after healing.” Therefore, appellants conclude that the stimulative effects on the proliferation of corneal keratocytes [disclosed by Mita, column 1, lines 26-31] and effects on the strength of a wound closure site are not inherently the same. The examiner does not address this argument.

We remind the examiner that an inherent limitation is one that is necessarily present; invalidation based on inherency is not established by “probabilities or possibilities.” Scaltech, Inc. v. Retec/Tetra, LLC., 178 F.3d 1378, 1384, 51 USPQ2d 1055, 1059 (Fed. Cir. 1999). Instead, it is the

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<sup>1</sup> The Cornea: Transactions of the World Congress on the Cornea III, pp. 15-21 (H. Dwight Cavanagh ed., Raven Press, New York)(1988).

examiner's burden, under these circumstances, to demonstrate that the disclosure in Mita is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function. Continental Can Co. In our opinion, based on the evidence of record, the examiner failed to meet his burden of demonstrating that the natural result of Mita's method would result in appellants' claimed method of increasing wound closure strength after corneal incision.

Adding additional weight to appellants' argument is their recognition that of the twelve types of ophthalmological surgery can be contemplated by Mita's use of the term "ophthalmological surgery, only two, cataract surgery and corneal transplantation involve corneal or sclerocorneal incision as required by appellants' claimed invention.

For the foregoing reasons, it is our opinion that Mita does not anticipate the claimed invention.

THE REJECTION UNDER 35 U.S.C. § 103:

As discussed supra, appellants have presented evidence demonstrating that a compound, such as Mita's (see column 1, lines 28-30, "the inventors found that these compounds have stimulative effects on the proliferation of corneal keratocytes") which exhibits a corneal wound healing effect by stimulating proliferation of corneal keratocytes does not always exhibit a strength of a wound closure site after healing. We remind the examiner that "[w]hen prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over." In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143,

147 (CCPA 1976). “If a prima facie case is made in the first instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed.” In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986). On this record, the examiner makes no attempt to rebut appellants’ argument and evidence, demonstrating that “the stimulative effects on the proliferation of corneal keratocytes and effects on the strength of a wound closure site are not inherently the same.” Brief, pages 7-8.

For the foregoing reasons, it is our opinion that the claimed invention is not obvious over Mita.

#### CONCLUSION

The rejection of claims 4, 5, 8-15, 21, and 24-30 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103 as obvious over Mita is reversed.

#### REVERSED

Donald E. Adams	)	
Administrative Patent Judge	)	
	)	
	)	BOARD OF PATENT
Demetra J. Mills	)	
Administrative Patent Judge	)	APPEALS AND
	)	
	)	INTERFERENCES
Lora M. Green	)	
Administrative Patent Judge	)	

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